Points to Consider (PtC) When Preparing TSCA New Chemical Notifications

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Outline of Draft PtC

I. Purpose
II. General Information Requirements
III. New Chemical Process
IV. Risk Calculations
V. Focus meeting
VI. Standard Review
VII. Post-Submission
VIII. Pilot and comments received

I. Purpose

- PtC provides concise guidance to improve PMN submissions – largely based on existing documentation, e.g., Sustainable Futures (SF)
  - PtC should reduce delays and back and forth with submitters
  - Two common problems in submissions
    - Provided information does not allow for refinement of risk assessment
    - Useful information that is in the submitter's possession is not provided at all → e.g., analog data
- Document sent out to industry participants for comment and as part of a pre-notice communication pilot

II. General Information Requirements

- Chemical identity
- Production, import and use
- There is not a base set of guideline testing (pchem, fate, ecotoxicity, human health) that must be provided

III.a. New Chemical Process

- Focus on information that can improve and expedite review
  - Consider a pre-notice consultation meeting
    - "Lower tier" than full PMN review
- Covers all sections of risk assessment including chemistry, hazard, worker/consumer/general population exposure, environmental fate and ecological exposure
- Includes descriptions of assumptions that are commonly made in the absence of information

III.b. New Chemical Process

- Know your chemical
  - Begin with p-chem followed by partitioning, absorption, metabolism, degradation…
  - Understand the chemical type for the submission and the relevant issues
    - Is the chemical likely to hydrolyze → the degradants will be important for ecotoxicity
    - Does your chemical fit in a new chemical category → Consider the described testing to determine potential data needs

III.c. New Chemical Process

- Examples of useful information
  - Particle size distribution
    - Strongly impacts worker exposure
      - Should target form of chemical that workers may be exposed to
    - In the absence of data, particles are assumed to be respirable
  - Descriptions of process information, particularly at submitter controlled sites
    - In the absence of data, EPA generic scenarios will be used to estimate worker exposures and releases → these estimates are intended to be conservative

III.d. New Chemical Process

- Human health hazard and ecotoxicity
  - Use physical chemistry to understand absorption and routes of exposure
  - Search for analogs and structural alerts
  - Know your chemical → understand metabolites and degradants
  - Is the data based on a guideline or related method
    - If not, EPA may ask for sufficient rationale for its use in the new chemical program
      - Non-guideline studies may be acceptable in certain situations

IV. Risk Calculations, V. Focus Meeting and VI. Standard Review

- Human health risk
  - Risk based on MOE for non-cancer (e.g., neurotoxicity) and slope factor for cancer
- Ecological risk
  - Acute aquatic risk – one day surface water concentration exceeds acute CoC
  - Chronic aquatic risk – twenty days or more of surface water exceedance above chronic CoC
- Focus meeting
  - Finalization of the initial risk assessment for the PMN
- Standard review
  - More in depth review of hazards and exposures for cases with complex concerns

VII. Post Submission Communication

- Please notify program manager of new submissions
  - Delays can occur due to large volume of communications across new chemical submissions
  - Please consider descriptive file names and separation of data into appropriate pieces when using CDX
- Consider use of binding option
- EPA may ask that you refine estimates of release and exposure based on
  - Control technology
  - Worker protections
  - Process descriptions
  - Use information

Additional Information

- Documentation was developed for the Sustainable Futures program
  - Contains description of most of the risk assessment process including models and tools
  - Gives insights on what types of engineering processes and releases will be calculated
  - EPA may request a rationale for changing release parameters away from the defaults typically entered into ChemSTEER™

Comments Received on PtC

- EPA received comments from industry participants to improve clarity and utility of PtC
- Some comments requested expanded scope, but this is meant to be a concise introduction → see references for more details

Comments Received on PtC

- Several comments on use of model vs submitted data on the new chemical substance or analog data
  - Risk assessment data hierarchy
    - High quality information on the PMN
    - High quality information on endpoint appropriate analog
    - Modeled data
- Why isn't submitted toxicity data used?
  - Possible flaws in study or insufficient description of test material or system
  - Submitted data doesn't address all of the needed endpoints

    → Data submitted for algae and daphnia but modeled data indicates highest hazard concern for fish

Comments Received on PtC

- EPA should provide a complete list of needed testing during pre-notice consultations
  - EPA is not in a position to provide a complete list at the pre-notice consultation stage
  - Testing recommendations for TSCA are commonly based on risk concerns via exposure pathways to identified populations (worker, consumer, general population, eco)

  → This requires all the steps of the risk assessment process, and these are not performed during the pre-notice consultation stage

Comments Received on PtC

- Requests for lists of worst case assumptions
  - Described in the Sustainable Futures material and defaults for the tools and models
    - ECOSAR™ and EPISuite™ have been programmed to provide conservative estimates
    - ChemSTEER™ allows for creation of conservative worker/release assessments
    - E-FAST™ can be run with SIC code options to evaluate low Stream-flow scenarios and the CEM model defaults to conservative consumer exposure assessments

Next Steps

- EPA plans to seek further comments
- After meeting all pre-publication requirements, EPA will update draft PtC document and create an official version for use
- Once finalized, EPA encourages the use of the PtC document and pre-notice consultations to improve the efficiency of the new chemical program